DEPARTMENT OF HEALTH & HUMAN SERVICES

M3604n

Food and Drug Administration
Seattle District
Pacific Region
22201 23rd Drive S.E.
Bothell, WA 98021-4421

Telephone: 425-486-8788
FAX: 425-483-4996

April 3, 2000

VIA FEDERAL EXPRESS

In reply refer to Warning Letter SEA 00-37

Mr. Takashi Shinosaka
President
Kibun Foods (U.S.A.), Inc.
1111 Third Avenue, Suite 1860
Seattle, Washington 98101

WARNING LETTER

Dear Mr. Shinosaka:

On January 14, 2000, Shannon L. Lowe conducted an inspection of your firm. The inspection was conducted to determine your firm's compliance with FDA's seafood processing regulations [21 Code of Federal Regulations (CFR) 123]. The seafood processing regulations, which became effective on December 18, 1997, require that you have and implement written verification procedures to verify that your foreign suppliers have implemented a preventive system of food safety controls known as Hazard Analysis Critical Control Point (HACCP) in accordance with U.S. requirements.

The product covered during this inspection was fresh yellowfin tuna loins from [redacted] At the conclusion of that inspection, a list of violations (Form FDA 483) was presented to Tadahiko Mitsui, Manager, New Product Development. These violations cause your imported products to be adulterated within the meaning of section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act. Specifically:

> You must have product specifications that are designed to ensure that the fish and fishery products you import are not injurious to health, to comply with 21 CFR 123.12(a)(2)(I). However, your firm does not have a product specification for fresh tuna imported from [redacted]
>
> You must implement an affirmative step that ensures that the fish and fishery products you import are processed in accordance with the seafood HACCP regulations, to comply with 21 CFR 123.12(a)(2)(ii). However, you firm did not perform an affirmative step for fresh tuna manufactured by [redacted]

The above HACCP violations are not meant to be an all-inclusive list of deficiencies at your firm. It is your responsibility to assure that all of your products are in compliance with applicable statutes enforced by the FDA. You should take prompt action to correct all of the violations. Failure to promptly correct these violations may result in regulatory action without further notice such as seizure and/or injunction. Furthermore, your firm and the foreign processor may be placed on import alert and future shipments of the product may be subject to detention without physical examination.

You should notify this office in writing, within 15 working days of the receipt of this letter, of the specific steps you have taken to correct the noted violations. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed. Your reply to these concerns should be addressed to Thomas S. Piekarski, Compliance Officer, at the address given above.

Sincerely,

Charles M. Breen
District Director

Enclosures:
Form FDA 483
21 CFR 123.12
Section 402(a)(4) of the Federal Food, Drug &Cosmetic Act

Cc: Tadahiko Mitsui
Manager, New Product Development
Kibun Foods (U.S.A.), Inc.
1111 Third Avenue, Suite 1860
Seattle, Washington 98101